



VERSION WITH MARKINGS TO SHOW CHANGES MADE

Do
Not
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My
1/28/05

This marked-up version was prepared with DeltaView software (v2.7). In this section, added text is marked with double underlining. *e.g.* added text, and deleted text is marked by a single strikethrough, *e.g.* ~~deleted text~~.

IN THE SPECIFICATION

The paragraph beginning at page 53, line 1 and ending at page 53, line 5 has been amended as follows:

Example VIII: Mixture Solution

The formulations of Examples VIII, IX, X, XI, and XXII include aqueous soluble bismuth sulfate~~chelate~~. In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth sulfate sufficient to provide the indicated amount of bismuth sulfate.

The paragraph beginning at page 53, line 6 and ending at page 53, line 14 has been amended as follows:

Solution dosage forms that were prepared according to the following guidelines did not show any

precipitation at any pH within the selected desired range of pH values.

| | |
|--------------------------------------------|-------|
| UDCA | 5 g |
| CDCA | 5 g |
| Bismuth eitrates <u>sulfate</u> | 5 g |
| Corn syrup solid | 260 g |
| Citric acid | q.s. |
| Purified water to make | 1.0 L |

The paragraph beginning at page 53, line 15 and ending at page 53, line 19 has been amended as follows:

The UDCA and CDCA were first dissolved in 1.5 mL of a 1N NaOH solution. Next, to the resulting clear solution were added the bismuth ~~eitrates~~sulfate and 150 mL of water. Then, the corn syrup solid was added portion by portion with vigorous agitation. The resulting solution was titrated to pH 4 with citric acid. Purified water was added to adjust the total volume to 1.0 L.

The paragraph beginning at page 54, line 1 and ending at page 54, line 10 has been amended as follows:

Example IX: UDCA-Syrup (20 g UDCA/L)

Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.

| | |
|--------------------------------|-------|
| UDCA | 20 g |
| 1 N NaOH | 60 mL |
| Maltodextrin | 700 g |
| Bismuth citrate <u>sulfate</u> | 4 g |
| Citric acid or lactic acid | q.s. |
| Purified water to make | 1.0 L |

The paragraph beginning at page 55, line 1 and ending at page 55, line 10 has been amended as follows:

Example X: UDCA-Syrup (20 g UDCA/L)

Solution dosage forms that were prepared according to the following guidelines did not show any

precipitation at any pH within the selected desired range
of pH values.

| | |
|-------------------------------------------|---------|
| UDCA | 20 g |
| 1 N NaOH | 60 mL |
| Corn syrup solid | 1,050 g |
| Bismuth citrate <u>sulfate</u> | 4 g |
| Citric acid or lactic acid | q.s. |
| Purified water to make | 1 L |

The paragraph beginning at page 56, line 1 and ending at page 56, line 9 has been
amended as follows:

Example XI: UDCA-Thick Syrup (30 g UDCA/L)

Solution dosage forms that were prepared
according to the following guidelines did not show any
precipitation at any pH within the selected desired range
of pH values.

| | |
|----------|-------|
| UDCA | 30 g |
| 1 N NaOH | 90 mL |

| | |
|----------------------------|------------|
| <u>Bismuth sulfate</u> | <u>4 g</u> |
| Maltodextrin | 1,050 g |
| Citric acid or lactic acid | 50 g |
| Purified water to make | 1.0 L |

The paragraph beginning at page 57, line 1 and ending at page 57, line 9 has been amended as follows:

Example XII: UDCA-Thick Syrup (30 g UDCA/L)

Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.

| | |
|----------------------------|------------|
| UDCA | 30 g |
| 1 N NaOH | 90 mL |
| <u>Bismuth sulfate</u> | <u>4 g</u> |
| Corn syrup solid | .1,500 g |
| Citric acid or lactic acid | 50 g |
| Purified water to make | 1.0 L |

The paragraph beginning at page 58, line 1 and ending at page 58, line 5 has been amended as follows:

Example XIII: UDCA-Paste (45 g UDCA/L)

The formulations of Examples XIII, XIV, XV, XVI, XVII, and ~~XVI~~XVIII include bismuth citrate as chelate. In each of these examples, solution dosage forms were prepared by adding an amount of an ammonium salt of bismuth citrate sufficient to provide the indicated amount of bismuth citrate.

The paragraph beginning at page 60, line 1 and ending at page 60, line 9 has been amended as follows:

Example XIV: UDCA-Paste (45 g UDCA/L)

Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.

| | |
|------------------------|-------------|
| UDCA | 45 g |
| 1 N NaOH | 135 mL |
| <u>Bismuth citrate</u> | <u>10 g</u> |

| | |
|----------------------------|---------|
| Corn syrup solid | 2,300 g |
| Citric acid or lactic acid | 50 g |
| Purified water to make | 1.0 L |